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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,830	12/08/2000	Junji Hamuro	200488US0CONT	6052
22850	7590	10/04/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/731,830	HAMURO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 80-132 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 93-105 and 119-132 is/are allowed.
- 6) ☒ Claim(s) 80-89 and 106-115 is/are rejected.
- 7) ☒ Claim(s) 90-92 and 116-118 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/334,637;09/181,881.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 80-132 are pending.

Applicants' amendment filed July 6, 2004 is acknowledged. Applicants' response has been fully considered. Claims 48-79 have been cancelled, and new claims 80-132 have been added. Therefore, claims 80-132 are examined.

### **Objection Withdrawn**

2. The previous objection of claims 54, 56-58, 60-62, 64-71, 74 and 78 is withdrawn in view of applicants' cancellation of the claim in the amendment filed July 6, 2004.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 102***

3. The previous rejection of claims 48-53, 55, 59, 63, 72, 73, 75-77 and 79 under 35 U.S.C. 102(b) as being anticipated by Andersson *et al.* (WO 91/18594) is withdrawn in view of applicant's cancellation of the claim in the amendment filed July 6, 2004.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 84 and 110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claim 84 recites the limitation "rheumatoid arthritis" in line 2. There is insufficient antecedent basis for this limitation in the claim because the independent claim, claim 80 only recites gastrointestinal inflammatory disease, hepatitis or hepatic cirrhosis, it does not recite rheumatoid arthritis. See also claim 110.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 80-89 and 106-115 are rejected under 35 U.S.C. 103(a) as obvious over Andersson *et al.* (WO 91/18594).

Andersson *et al.* teach using cystine compounds such as N,N'-diacetylcystine dimethyl ester (diMeNAC), N,N'-diacetylcystine diethyl ester (diEtNAC), and N,N'-diisovalerylcystine dimethyl ester (diMeVAL; page 3, line 31-page 4, line 33) in an effective amount to treat

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diseases where a defect in the immune system such as chronic bronchitis and other inflammatory diseases of airway, certain autoimmune diseases such as rheumatoid arthritis (claims 84 and 110) and various malignant diseases by administering to a host in need of such treatment (page 6; claim 24 of the WO document). Although the reference does not specifically indicates gastrointestinal inflammatory disease, hepatitis or hepatic cirrhosis are diseases due to a defect in the immune system, the specification of the instant application discloses gastrointestinal inflammatory disease, hepatitis and hepatic cirrhosis are immunological diseases (see page 1, lines 9-13), thus at the time of invention was made, it would have been obvious that one of ordinary skill in the art is motivated to treat gastrointestinal inflammatory disease, hepatitis and hepatic cirrhosis with cystine compounds (claims 80-83, 87-89, 106-109, 113-115), which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made. Since the reference teaches the same amount of cystine compound (0.5-500 mg/day; page 9, line 1) is used to administer to the subject as the instant application (1-5000 mg/day; page 19, lines 10-11 of the specification), it would be expected to induce a Th2 response in the subject such as reducing the content of reductive glutathione in macrophage, increasing the capability of the macrophage to produce IL-6, and decreasing the capability of the macrophage to produce IL-12 and NO (claims 85-86); or to suppress cellular immune responses in the subject such as reducing the content of reductive glutathione in macrophage (claims 111-112).

#### ***Claim Objection***

7. Claims 90-92 and 116-118 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*Conclusion*

8. Claims 80-89 and 106-115 are rejected, and claims 90-92 and 116-118 are objected to. It appears that claims 93-105 and 119-132 are free of art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

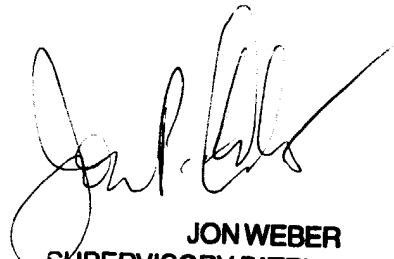
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

cmk

CMK  
September 23, 2004

  
**JON WEBER**  
SUPERVISORY PATENT EXAMINER